Remarks

This is a response to the final Office Action dated November 4, 2005. Claims 10-49 were pending in the subject application with claims 10-21 withdrawn from consideration. By this Amendment, claims 29, 30, 39, 40, and 48 have been amended. The undersigned avers that no new matter is introduced by this Amendment. Entry and consideration of the Amendments presented herein is respectfully requested. Claims 10-21 remain pending but withdrawn from consideration. Accordingly, claims 22-49 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Claims 22-24, 30-34, 40-43, and 48-49 have been rejected under 35 U.S.C. §103(a) as being obvious over Augart *et al.* (U.S. Patent No. 6,054,482) in view of Berge *et al.* (*J. Pharm. Sci*, 1977, 66:1-18). This rejection has been substantively maintained from a previous Office Action. In view of a recently published reference, the Applicants respectfully traverse.

The Augart *et al.* patent describes crystallized hydrochloride salt of 1-(aminomethyl)-cyclohexaneacetic acid (gabapentin). As acknowledged at page 2 of the first Office Action, dated April 28, 2005, the Augart *et al.* patent does not disclose any of the organic acid salts of gabapentin recited in the currently pending claims, *i.e.*, tartaric acid, ethanedisulfonic acid, and maleic acid. The first Office Action also cites the Berge *et al.* publication for disclosing the advantage of pharmaceutically acceptable addition salts and a list of FDA approved salts, which includes hydrochloride, tartrate (tartaric acid), edisylate (ethanedisulfonic acid), and maleate (maleic acid). The Examiner indicates that one of ordinary skill in the art would have been motivated to prepare the claimed compounds in the recited salt form because they were generically approved by the Food and Drug Administration (FDA) as suitable for pharmaceutical use.

Since the final Office Action, dated November 4, 2005, was mailed, a reference was published which further validates Applicants' argument for the non-obviousness of preparing the claimed salts. According to Variankaval *et al.* (*Crystal Growth & Design*, 2006, page A, left column, published on the Internet on January 21, 2006), "At present there exists no a priori prediction procedure to determine the feasibility of salt formation in a given acid-base pair".

This statement clearly describes the unpredictable nature of salt formation in specific cases. If this is presently the case, it must have also been the case as of the filing date of the instant application. Given such unpredictability, the teaching of a novel and specific salt form undoubtedly rises to the level of an unexpected result and refutes the Examiner's argument of obviousness. *Crystal Growth & Design* is a peer-reviewed journal which is well-respected in the field of crystalline materials. Applicants have not cited this reference previously since it was only published on January 21, 2006.

The Examiner has rejected the pending claims under 35 U.S.C. § 103(a) by combining two references, Augart *et al.* (US 6,054,482) in view of Berge *et al.* (J. Pharm. Sci.). There is no motivation to combine the recited references and in addition, in view of the recently published reference, there is no reasonable expectation by the person of ordinary skill in the art that the above cited salts of gabapentin will successfully form.

In the alternative, if the Examiner does not accept Applicants argument in view of the Variankaval reference, and an organic acid salt of a freebase is deemed obvious, it is not obvious that the resultant salt would be crystalline. Even where there exists a high likelihood of salt formation, the physical state of the salt (i.e., amorphous or crystalline) cannot be predicted.

Claims 22-49 have been rejected under 35 U.S.C. §103(a) as being obvious over Augart *et al.* (U.S. Patent No. 6,054,482) in view of Berge *et al.* (*J. Pharm. Sci*, 1977, 66:1-18), and further in view of US Pharmacopia #23 (National Formulary #18, 1995, pp. 1843-1844) and Rouhi (*Chem. Eng. News*, Feb. 2004, pp. 32-35). This rejection has been substantively maintained from a previous Office Action. In view of the arguments delineated supra, the Applicants respectfully traverse.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

In view of the foregoing remarks, the newly cited reference, and amendments to the claims, the Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 50-2626.

The Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

_____, 2006

By: _____
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Attachment: Variankaval publication (*Crystal Growth & Design*, 2006, 0:A-K)